Reprinted
January 28, 2004

SENATE BILL No. 113

DIGEST OF SB 113 (Updated January 27, 2004 3:38 pm - DI 110)

Citations Affected: IC 16-28; IC 25-26; IC 34-30; noncode.

Synopsis: Distribution of unused drugs. Allows a pharmacy or pharmacist to donate medication to certain health clinics. Establishes the regional drug repository program to distribute donated drugs. Requires a health facility to return certain unused medication to the pharmacy that dispensed the medication. Allows a pharmacy or pharmacist to accept returned medication from a hospice program. Requires the office of Medicaid policy and planning to review the process of returning unused medication.

Effective: July 1, 2004.

Dillon

January 6, 2004, read first time and referred to Committee on Health and Provider Services.
January 22, 2004, amended, reported favorably — Do Pass.
January 27, 2004, read second time, amended, ordered engrossed.

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Second Regular Session 113th General Assembly (2004)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2003 Regular Session of the General Assembly.

SENATE BILL No. 113

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 16-28-11-4 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2004]: **Sec. 4. A health facility that possesses unused medication that meets the requirements of IC 25-26-13-25(i)(1) through IC 25-26-13-25(i)(6):**

(1) shall return medication that belonged to a Medicaid recipient; and

(2) may return other unused medication;

to the pharmacy that dispensed the medication.

SECTION 2. IC 25-26-13-25, AS AMENDED BY P.L.182-2003, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2004]: Sec. 25. (a) All original prescriptions, whether in written or electronic format, shall be numbered and maintained in numerical and chronological order, or in a manner approved by the board and accessible for at least two (2) years in the pharmacy. A prescription transmitted from a practitioner by means of communication other than writing must immediately be reduced to

writing or recorded in an electronic format by the pharmacist. The files shall be open for inspection to any member of the board or its duly authorized agent or representative.

(b) Except as provided in subsection (c), ~~before the expiration of subsection (c) on June 30, 2003,~~ a prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may not be refilled without written or oral authorization of a licensed practitioner.

(c) A prescription for any drug, the label of which bears either the legend, "Caution: Federal law prohibits dispensing without prescription" or "Rx Only", may be refilled by a pharmacist one (1) time without the written or oral authorization of a licensed practitioner if all of the following conditions are met:

(1) The pharmacist has made every reasonable effort to contact the original prescribing practitioner or the practitioner's designee for consultation and authorization of the prescription refill.

(2) The pharmacist believes that, under the circumstances, failure to provide a refill would be seriously detrimental to the patient's health.

(3) The original prescription authorized a refill but a refill would otherwise be invalid for either of the following reasons:

(A) All of the authorized refills have been dispensed.

(B) The prescription has expired under subsection (f).

(4) The prescription for which the patient requests the refill was:

(A) originally filled at the pharmacy where the request for a refill is received and the prescription has not been transferred for refills to another pharmacy at any time; or

(B) filled at or transferred to another location of the same pharmacy or its affiliate owned by the same parent corporation if the pharmacy filling the prescription has full access to prescription and patient profile information that is simultaneously and continuously updated on the parent corporation's information system.

(5) The drug is prescribed for continuous and uninterrupted use and the pharmacist determines that the drug is being taken properly in accordance with IC 25-26-16.

(6) The pharmacist shall document the following information regarding the refill:

(A) The information required for any refill dispensed under subsection (d).

(B) The dates and times that the pharmacist attempted to contact the prescribing practitioner or the practitioner's

designee for consultation and authorization of the prescription refill.

(C) The fact that the pharmacist dispensed the refill without the authorization of a licensed practitioner.

(7) The pharmacist notifies the original prescribing practitioner of the refill and the reason for the refill by the practitioner's next business day after the refill has been made by the pharmacist.

(8) Any pharmacist initiated refill under this subsection may not be for more than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day. However, a pharmacist may dispense a drug in an amount greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day if:

(A) the drug is packaged in a form that requires the pharmacist to dispense the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day; or

(B) the pharmacist documents in the patient's record the amount of the drug dispensed and a compelling reason for dispensing the drug in a quantity greater than the minimum amount necessary to supply the patient through the prescribing practitioner's next business day.

(9) Not more than one (1) pharmacist initiated refill is dispensed under this subsection for a single prescription.

(10) The drug prescribed is not a controlled substance.

A pharmacist may not refill a prescription under this subsection if the practitioner has designated on the prescription form the words "No Emergency Refill".

(d) When refilling a prescription, the refill record shall include:

(1) the date of the refill;

(2) the quantity dispensed if other than the original quantity; and

(3) the dispenser's identity on:

(A) the original prescription form; or

(B) another board approved, uniformly maintained, readily retrievable record.

(e) The original prescription form or the other board approved record described in subsection (d) must indicate by the number of the original prescription the following information:

(1) The name and dosage form of the drug.

(2) The date of each refill.

(3) The quantity dispensed.

(4) The identity of the pharmacist who dispensed the refill.

(5) The total number of refills for that prescription.

(f) A prescription is valid for not more than one (1) year after the original date of issue.

(g) A pharmacist may not knowingly dispense a prescription after the demise of the practitioner, unless in the pharmacist's professional judgment it is in the best interest of the patient's health.

(h) A pharmacist may not knowingly dispense a prescription after the demise of the patient.

(i) A pharmacist or a pharmacy shall not resell, reuse, or redistribute a medication that is returned to the pharmacy after being dispensed unless the medication:

(1) was dispensed to a patient:

(A) residing in an institutional facility (as defined in ~~856 IAC 1-28-1(a));~~ **856 IAC 1-28.1-1(6)); or**

(B) in a hospice program under IC 16-25;

(2) was properly stored and securely maintained according to sound pharmacy practices;

(3) is returned unopened and:

(A) was dispensed in the manufacturer's original:

(i) bulk, multiple dose container with an unbroken tamper resistant seal; or

(ii) unit dose package; or

(B) was packaged by the dispensing pharmacy in a:

(i) multiple dose blister container; or

(ii) unit dose package;

(4) was dispensed by the same pharmacy as the pharmacy accepting the return;

(5) is not expired; and

(6) is not a controlled substance (as defined in IC 35-48-1-9), unless the pharmacy holds a Type II permit (as described in ~~IC 25-26-13-17).~~ **section 17 of this chapter).**

(j) A pharmacist may use the pharmacist's professional judgment as to whether to accept medication for return under ~~subsection (i).~~ **this section.**

(k) A pharmacist who violates subsection (c) commits a Class A infraction.

SECTION 3. IC 25-26-20 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2004]:

Chapter 20. Regional Drug Repository Program

Sec. 1. The definitions in IC 25-26-13-2 apply throughout this chapter.

Sec. 2. As used in this chapter, "nonprofit health clinic" means any of the following:

(1) A federally qualified health center (as defined in 42 U.S.C. 1396d(l)(2)(B)).

(2) A rural health clinic (as defined in 42 U.S.C. 1396d(l)(1)).

(3) A nonprofit health clinic that provides medical care to patients who are indigent, uninsured, or underinsured.

Sec. 3. (a) The board may organize a voluntary regional drug repository program to collect and redistribute drugs to nonprofit health clinics.

(b) The board may enter into a voluntary agreement with any of the following to serve as a regional drug repository:

(1) A pharmacist or pharmacy.

(2) A wholesale drug distributor.

(3) A hospital licensed under IC 16-21.

(4) A health care facility (as defined in IC 16-18-2-161).

(5) A nonprofit health clinic.

(c) A regional drug repository may not receive compensation for participation in the program.

Sec. 4. (a) Except as provided in subsections (b) and (c), unadulterated drugs that meet the requirements set forth in IC 25-26-13-25(i) may be donated without a prescription or drug order to the regional drug repository program by the following:

(1) A pharmacist or pharmacy.

(2) A wholesale drug distributor.

(3) A hospital licensed under IC 16-21.

(4) A health care facility (as defined in IC 16-18-2-161).

(5) A hospice.

(6) A practitioner.

(b) An unadulterated drug that:

(1) was returned under IC 25-26-13-25; and

(2) was prescribed for a Medicaid recipient;

may not be donated under this section.

(c) A controlled drug may not be donated under this section unless the Medicaid program has been credited for the product cost of the drug as provided in policies under the Medicaid program.

Sec. 5. (a) A drug that is given by a regional drug repository to a nonprofit health clinic may not be:

(1) sold; or

(2) given to a patient, except upon a practitioner's prescription or drug order.

(b) An individual who is eligible to participate in:

(1) the state Medicaid program under IC 12-15; or

(2) a program that:

(A) provides a prescription drug benefit; and

(B) is funded in whole or in part by state funds;

is not eligible to receive a drug donated under the voluntary regional drug repository program organized under section 3 of this chapter.

Sec. 6. (a) The following are not subject to liability under IC 34-20-2-1:

(1) A person or entity who donates a drug to a regional drug repository program under this chapter in accordance with rules adopted by the board under section 7 of this chapter.

(2) A non-profit health clinic or practitioner who accepts or dispenses a drug under the regional drug repository program in accordance with rules adopted by the board under section 7 of this chapter.

(3) A regional drug repository that distributes a drug under the program in accordance with rules adopted by the board under section 7 of this chapter.

(b) Except in cases of negligence or willful misconduct by the manufacturer, a drug manufacturer is not subject to liability under IC 34-20-2-1 for a claim arising from a drug that is donated, accepted, or dispensed under this chapter to the user or the consumer.

Sec. 7. The board may adopt rules under IC 4-22-2 to:

(1) establish standards and procedures for accepting, storing, and dispensing drugs donated under this chapter;

(2) establish the types of drugs that may be donated; and

(3) administer this chapter.

SECTION 4. IC 34-30-2-101.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2004]: **Sec. 101.5. IC 25-26-20-6 (Concerning drugs donated to a regional drug repository program).**

SECTION 5. [EFFECTIVE JULY 1, 2004] **(a) As used in this SECTION, "office" refers to the office of Medicaid policy and planning established by IC 12-8-6-1.**

(b) Before January 1, 2005, the office shall review the process of returning unused medication under IC 25-26-13-25, as amended by this act, and the process of reimbursing the office for unused medication of a Medicaid recipient. The office may consider in the office's review information provided by pharmacies that provide

long term care pharmacy services. Beginning December 31, 2004, the office may review the process of returning unused medication when the office determines that a review is necessary.

(c) Before October 1, 2004, the office shall provide any information gathered under subsection (b) to the health finance commission established by IC 2-5-23-3. Before November 1, 2004, the health finance commission shall review the process of returning unused medication under IC 25-26-13-25, including the reimbursement to the office for the unused medication of a Medicaid recipient.

(d) This SECTION expires December 31, 2009.

COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 113, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 5, delete line 14.

Page 5, line 15, delete "(3)" and insert "**(2)**".

Page 5, line 16, delete "(4)" and insert "**(3)**".

Page 5, line 17, delete "(5)" and insert "**(4)**".

Page 5, line 18, delete "(6)" and insert "**(5)**".

Page 5, delete lines 19 through 20.

Page 5, line 21, delete "(d)" and insert "**(c)**".

Page 5, line 24, delete "drugs, including a medication that has been" and insert "**drugs that meet the requirements set forth in IC 25-26-13-25(i)**".

Page 5, line 25, delete "returned under IC 25-26-13-25(i),".

Page 5, delete line 29.

Page 5, line 30, delete "(3)" and insert "**(2)**".

Page 5, line 31, delete "(4)" and insert "**(3)**".

Page 5, line 32, delete "(5)" and insert "**(4)**".

Page 5, line 33, delete "(6)" and insert "**(5)**".

Page 5, line 34, delete "(7)" and insert "**(6)**".

Page 5, line 39, delete "schedule II drug listed in IC 35-48-2-6" and insert "**controlled drug**".

Page 5, line 41, after "5." insert "**(a)**".

Page 6, between lines 3 and 4, begin a new paragraph and insert:

"**(b) An individual who is eligible to participate in:**

(1) the state Medicaid program under IC 12-15; or

(2) a program that:

(A) provides a prescription drug benefit; and

(B) is funded in whole or in part by state funds;

is not eligible to receive a drug donated under the voluntary regional drug repository program organized under section 3 of this chapter.".

Page 6, line 5, delete "person, other than a drug manufacturer," and insert "**person**".

Page 6, line 14, delete "bad faith or".

Page 6, line 14, after "a" insert "**prescription**".

Page 6, line 15, delete "is not liable for a claim or an injury, civil or" and insert "**shall not be subject to criminal or civil liability for**

injury, death, or loss to person or property arising from the donation, acceptance, dispensing, or transfer of a prescription drug that is manufactured by the prescription drug manufacturer and donated by a person under this chapter. This section includes immunity for a prescription drug manufacturer from liability for:

(1) the failure to store, transfer, or maintain a prescription drug;

(2) the failure to transfer or communicate product or consumer prescription drug information; or

(3) the failure to convey the expiration date of the prescription drug;

after the drug is donated under this chapter.".

Page 6, delete lines 16 through 17.

and when so amended that said bill do pass.

(Reference is to SB 113 as introduced.)

MILLER, Chairperson

Committee Vote: Yeas 10, Nays 0.

SENATE MOTION

Madam President: I move that Senate Bill 113 be amended to read as follows:

Page 5, line 34, delete "section." and insert "**section unless the Medicaid program has been credited for the product cost of the drug as provided in policies under the Medicaid program.**".

Page 6, delete lines 6 through 32, begin a new paragraph and insert:

"**Sec. 6. (a) The following are not subject to liability under IC 34-20-2-1:**

(1) A person or entity who donates a drug to a regional drug repository program under this chapter in accordance with rules adopted by the board under section 7 of this chapter.

(2) A non-profit health clinic or practitioner who accepts or dispenses a drug under the regional drug repository program in accordance with rules adopted by the board under section 7 of this chapter.

(3) A regional drug repository that distributes a drug under the program in accordance with rules adopted by the board under section 7 of this chapter.

(b) Except in cases of negligence or willful misconduct by the manufacturer, a drug manufacturer is not subject to liability under IC 34-20-2-1 for a claim arising from a drug that is donated, accepted, or dispensed under this chapter to the user or the consumer.".

(Reference is to SB 113 as printed January 23, 2004.)

DILLON